Secl. II-27—100,000—31-5-38.

E & P.H (1948) Department.

SERIES.

G.O. No. 3391. P.H

Dated 5-10-48

[Despatch Abstract.]

DRUGS -Madras Drugs Rules, 1945 - Suggestions for amendments to Schedule F Part XI items D, E & F -Communicated -

No.F.18-4/46-D.
Government of India,
Ministry of Health.

New Delhi, the 20th Sept.1948.

From
J.N. Saksena, Esq., B.A.,
Assistant Secretary to the Govt. of India,

To
The Secretary to the Govt. of Madras,
Education and Public Health Department,
Madras.

Subject: Drugs Rules 1945 -Suggestions for amendments to.

Sir,

I am directed to refer to Part XI items D, E and F of Schedule F to the Drugs Rules 1945, in which it is provided that the labels of Containers of the drugs in question should bear the words "not to be injected" and to say that the representations have been received by the Government of India stating that this provision is not only unnecessary but also rediculous in certain cases. Copies of two letters mentioned in the margin which have been received in this connection are enclosed for information. The Drugs Technical Advisory Board which considered this matter at their sixth meeting recommended that the words "not to be injected" should be substituted by the words "not for parenteral Administration", vide para 27 of the minutes (extract attached). The Board are however reconsidering the matter further vide para 8 of the Minutes of the seventh meeting forwarded with this Ministry's letter No.412-DS/48, dated the 19th March, 1948 and I am to request that pending receipt of their final views and a decision thereon the provision referred to above in Schedule F Part XI items D, E and F should not be enforced.

(1) Extract from letter dated 9-8-1946 from P.A.M.D.A.L.
(2) Letter No.C., dated 15.7.1948 from Messrs. Ciba Pharma Ltd., Bombay.

Yours faithfully,

(Sd.) J.N. Saksena,

Assistant Secretary.

Copy of letter No.C., dated the 15th July, 1948 from M/S Ciba Pharma Ltd., Bombay, to the Drugs Controller, India New Delhi.

Drug Rules 1945 under the Drugs Act 1940.

We refer to Part XI Clause E of the above rules regarding labelling of products containing Hormones. We are marketing Ovocyclin and Perandren in ointment form (Hormone Preparations) and would, therefore, like to know whether the labels of containers should bear the words "not to be injected".

Similarly in Part D against Vitamin preparations we have Biotose in capsules form. As in the above case, we wish to hear from you whether it is absolutely essential for us to indicate the words "not to be injected" on the labels of the packages.

Thanking you, we are,

Copyof letter dated the 9th August, 1946 from Messrs. The Pharmaceutical and Allied Manufacturers' and Distributors' Association Limited.

SCHEDULE F - Part XI: D.E.F. The Association is objecting to this clause, because it is considered absurd to label tablets, capsules and liquid preparations for oral use as 'not to be injected.' The Association presumes that this type of medicine will be handled by persons of at least average intelligence who, except for a very small number of diabetic patients, will not be in the habit of giving themselves injections. The Medical Profession is surely intelligent enough to know what should be injected and what should not. This clause if persisted in, will necessitate the labelling of a bottle of cod liver oil or a bottle of malt extract with added vitamins, as 'not to be injected' which in the opinion of this Association, is utterly ridiculous. We would also point out that all such oral preparations bear labels stating "One table spoon or teaspoon etc. to be taken 3 times a day" etc. so that it is quite clear that they are not for injection

We would welcome your advice on one additional point

RULE 109: Will you please clarify this rule, confirming that the date of manufacture must be marked on a container of a preparation for parenteral administration only whom included in the special list of items covered in Schedule F and not for other products not mentioned in Schedule F.

Extract from the Minute.

Questionof labelling vitamin preparations for oral use with the words 'Not to be injected'

27. According to the labelling provisions under item D of Part XI of Schedule F to the Drugs Rules,1945, it is necessary that preparations for oral use such as colloidal calcium with vitamin D and Liquor Adrenaline Hydrochloride etc. should be labelled "Not to be injected". It was mentioned that since there were positive provisions for labelling parenteral drugs, there was no need for nagative instructions in the case of medicines in a form not to be administered parenterally. On the other hand, it was argued that in the case of multivitamin tablets, etc. which are used for the dual purpose of oral and parenteral administration, it would be necessary to distinguish the nature of the preparation by labelling.

p.t.o.

A suggestion that the words "Not to be injected" was not agreed to as Cod Liver Oil and other substances are administered by routes other than oral. It was finally agreed that the words 'Not to be injected' should be substituted by "Not for parenteral administration".

GOVERNMENT OF MADRAS
Education and Public Health Deptt.
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G.O.(Ms.)No.3391, Public Health D/5-10-1948.

ABSTRACT

Drugs - Madras Drugs Rules, 1945 - Suggestions for amendments to Schedule F Part XI items D, E and F - Communicated

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READ:-

From the Government of India, No.F.18-4/46-D, dated 20-9-1948.

O R D E R:

Communicated to the Surgeon-General for information and necessary action.

(By Order of His Excellency the Governor)

(Sd.)xxxxx,
Secretary to Govt.

To
The Surgeon-General with the Govt. of Madras.
(with enclosure)

No.F.18-4/46-D.
Government of India,
Ministry of Health.

New Delhi, the 30th Dec.1948.

From
J.N.Saksena, Esq., Under Secretary to the Govt. of India.

To: All Provincial Governments.

Subject:- Drugs Rules, 1945 - Labelling of preparations containing vitamins, liver extracts and hormones in any form not to be administered parenterally.

Sir,

I am directed to refer to this Ministry's letter of even number dated the 20th September, 1948 on the subject mentioned above and to say that in view of further representations from the trade received in the matter f the Drugs Technical Advisory Board has been asked to consider afresh the question whether there is any need to amend Part XII items D, E & F of Schedule F to the Drugs Rules, 1945 so as not to require preparations containing vitamins, liver extracts and hormones, in any form not to be administered parenterally, to be labelled with the words 'not to be injected'; the matter will be considered by the Board at its next meeting. I am to request the Provincial Government to issue necessary instructions to the Provincial Drugs Controller that pending receipt of the final views of the Board and a decision thereon, the relevant provision in Part XII item D, E & F of Schedule F to the Drugs Rules, 1945 should not be enforced.

Yours faithfully,
(Sd.)J.N.Saksena,
Under Secretary.

/True copy/

Superintendent,
Madras Record Office.

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